OCT - 5 2001

510(k) Summary

Date:	September 15, 2001
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact: (714)730-5000	Paul Biggins, Regulatory Affairs Specialist,
Establishment Registration Number:	2020563
Device Proprietary Name:	Cerebral Blood Flow Analysis System (CBP), Model Number CSCP-001A
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	General Electric Perfusion CT 2 [K010042] Siemens Perfusion CT [K982536]
Reason For Submission	Modification of cleared device

Description of this Device:
The CSCP-001A is an image analysis software package, that will be applied to the Toshiba TSX-101A (Aquilion) and TSX-021A (Asteion) CT scnanners, that allows the user to process dynamic scan image data that are acquired in conjunction with a contrast bolus. The package allows visualization of the data in image map formats. Additionally, the package allows the display of numeric data via the image analysis software that is integral to the package. The software is post processing and does not control the x-ray features of the system.

Summary of Intended Uses:
The Cerebral Blood Perfusion Package is an application software that permits cerebral perfusion imaging based upon dynamic CT images that are acquired after the injection of contrast. The software allows for visualization of apparent blood

flow in brain tissue and pictorially illustrates perfusion parameters (CBP- cerebral blood perfusion, CBV cerebral blood volume, mtt - mean transit time, and ERR - CBP residual difference SD map) from a set of dynamic images. This package when used by a trained physician will assist in the assessment of the type and extent of cerebral perfusion disturbances. Additionally, the software allows for measurement of various values such as mean value, standard deviation, area and distance.

Technological Characteristics:
This package is similar in uses and applications as those of the predicate devices. The main difference is in the method used to obtain the final results. Both this and the predicate devices are used as post-processing software to images collected by the parent CT Scanner.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020.30 and 1020.33, that apply to this upgrade, will be met and reported via a supplement to the initial report for the predicate device. Additionally this system is in conformance with the applicable parts of the IEC-60601 - Medical Device Safety standards.

Substantial Equivalence:
Based upon the above considerations TAMS believes that this upgrade package, Cerebral Blood Flow Analysis System (CBP), Model Number CSCP-001A is substantially equivalent to the predicate devices. This package and the predicate devices are all post-processing and provide the same features of visualization and numeric data. Additionally this package and the predicate devices have the same indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2001

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
TUV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013214
Trade/Device Name: Cerebral Blood Flow Analysis Syster (CBP), Model Number CSCP-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 15, 2001
Received: September 26, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K013214

510(k) Number (if known): _____

Device Name: Cerebral Blood Flow Analysis System (CBP), Model Number CSCP-001A

Indications for Use:

The Cerebral Blood Perfusion Package is an application software that permits cerebral perfusion imaging based upon dynamic CT images that are acquired after the injection of contrast. The software allows for visualization of apparent blood flow in brain tissue and pictorially illustrates perfusion parameters (CBP- cerebral blood perfusion, CBV cerebral blood volume, mtt - mean transit time, and ERR - CBP residual difference SD map) from a set of dynamic images. This package when used by a trained physician will assist in the assessment of the type and extent of cerebral perfusion disturbances. Additionally, the software allows for measurement of various values such as mean value, standard deviation, area and distance.

Carolyn Y Neuland

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K013214

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____ RA

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

SK IF II